

### **Remarks/Arguments**

This amendment is in response to the Office Action dated September 22, 2005.

Claims 1, 2, 4-10 remain in this application. Claims 3 and 8-10 have been canceled. Claims 11- 15 have been added to further define the present invention. Support for claim 11 is found in claim 1 and claim 4. Support for the embodiments of claims 12-15 is found at Page 5, lines15-18 of the specification and in Figure 1.

Claims 1, 2, 3, 6 and 7 have been rejected under 35 USC 102(b) by Leason et al (US 5360413).

Applicants disagree.

The present invention requires a valve that has a face that is capable of forming a steamable face and a sterile barrier for the interior of the body and downstream components. Claims 6 and 7 further add that it be capable of at least one sterile connection.

Leason teaches only an aseptic barrier. See Col 3, lines 56-58 "Easy aseptic treatment is facilitated by the placement and configuration of the top surface of the piston 18 relative to the inlet opening 6." See also Col 3, lines 60-61,"In this manner a cotton ball with disinfectant on it can easily clean the entire surface of the piston....", See likewise Col 1, lines 53-55 "The design is conducive to standard septic cleaning of the piston ....".

Leason clearly and only teaches that its device is capable of aseptic cleaning. No where does it mention it is steamable, sterile or that it can form at least one sterile connection. Moreover as admitted by the office action in the rejection under 35 USC 103(a), Leason doesn't teach or suggest being able to be sterilized.

As anticipation is one of strict identity and as the cited reference fails to teach the claimed elements, the rejection under 35 USC 102(b) must be withdrawn as being unsupported by the teachings of the cited reference.

Claims 4 and 5 have been rejected under 35 USC 103(a) over Leason in view of Tessman et al (US 6210372). Applicants disagree.

The office action states claim 4 differs from Leason in that the device is plastic and that Claim 5 differs in that the device is made of polyetherimide. Tessman is said to teach the use of polyetherimide in devices and it would have been obvious from the cited combination to form the device of Leason of a thermoplastic, such as polyetherimide, so it could withstand sterilization.

One of ordinary skill in the art would not have considered the combination of Leason with Tessman. Leason specifically teaches its piston and stretchable member are formed of a stretchable material such as latex or silicone rubber or Krayton, Sanoprene or Hytrel (Col 5, lines 6-12). It's clear to one of skill in the art that this component would need to be so in order for the device of Leason to work. One would not have looked to a disclosure of hard non-resilient plastics as taught in Tessman for replacement materials used in a flexible, stretchy piston/sealing device. In doing so, one would render the device of Leason moot and unworkable. As such the cited combination is improper and cannot be combined as cited in the office action and the prima facie case of obviousness has not been established. As such, the rejection is respectfully requested to be withdrawn.

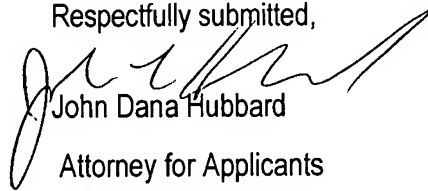
At best one would consider using a thermoplastic for the outer housing of Leason and a resilient material such as silicone for the parts that need to be flexible. Tessman does this as well. Note that compressive sleeve 140 is taught as being made of silicone rubber in the same section cited for support of the office action (Col 6, lines 59-60). Yet even that combination does not teach or

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suggest the present invention. As such the prima facie case of obviousness has been successfully rebutted and the claims are in condition for allowance.

Reconsideration and allowance of the remaining claims is respectfully requested in view of the foregoing remarks.

Respectfully submitted,



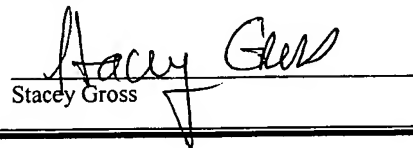
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Stacey Gross